

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Fred T. Lee Jr.
Serial No.: 10/796,239
Filed: March 9, 2004
For: MULTIPOLAR ELECTRODE SYSTEM FOR
VOLUMETRIC RADIOFREQUENCY ABLATION
Examiner: David M. Shay
Art Unit: 3769
Docket No.: 1512.166

REMARKS ACCOMPANYING
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In an Office Action dated April 2, 2010, the Examiner has rejected claims 1-9, 13, 16-22 and 28-32 as being unpatentable over the prior art. Specifically, independent claims 1, 16, and 30 have been rejected over a combination of Gough and Swanson.

This was the second or subsequent rejection with respect to these claims and therefore this case is ripe for appeal. Applicants have filed a Notice of Appeal simultaneously herewith.

The rejections contain clear errors and omissions of essential elements needed for a *prima facie* rejection. As such, Applicants hereby request that a pre-appeal brief review be conducted in accordance with the Pre-Appeal Brief Conference Pilot Program that was initiated on July 12, 2005 and extended indefinitely on January 10, 2006.

The present invention is an ablation probe for destroying tumor tissue in a patient by passing electricity through the tumor. The invention uses two sets of radially extending electrodes (“umbrella electrodes”) placed at different heights on a single shaft. Each set of electrodes defines a plane and the space between them on the shaft defines a volume. A two-shaft version of the invention (not currently claimed) is shown in Fig. 1 below, to illustrate the general configuration of the umbrella electrodes, and a cross-section of the claimed single-shaft probe is shown in Fig. 3 showing the insulation 46 on

the shaft between the electrodes 32 and 44 that produces a more uniform ablation volume.

FIG. 1

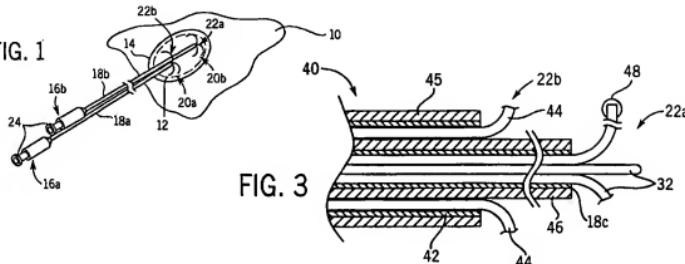


FIG. 3

The rejection of the claims principally relies on Gough '143, which in a first embodiment teaches a single set of three radial electrodes used alone, and which in a second embodiment teaches two sets of two radial electrodes on one shaft. See below.

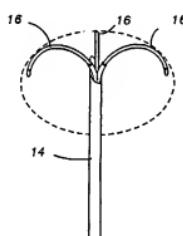


FIG. -4

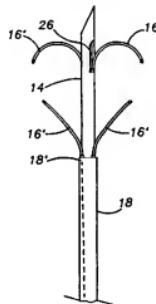


FIG. -8

Importantly, Gough does not teach placing insulation 44 on the shaft between the radially extending probes as claimed in the present invention. The Swanson reference is relied upon only for a particular frequency range and does not remedy this deficiency of Gough.

The Examiner has taken two approaches to addressing the fact that the cited references do not teach the claim limitation of an insulated shaft between the electrodes and, in fact, teaches an un-insulated shaft between the electrodes. See, the latest Office Action at page 23, lines 2-8.

First, the Examiner dismisses the significance of the missing claim limitation by stating that it is "not critical" and provides no "unexpected benefit". Criticality and unexpected benefits are not a requirement for patentability, nor has the Examiner provided foundation that he is qualified to determine what is critical or was unexpected at the time of the invention in this complex technology. Insulating the shaft between the electrodes is believed to improve the ablation pattern when electrodes are used in this bi-mode.

Alternatively, the Examiner suggests that those in the prior art would have been motivated to add insulation to metal needle shafts to make them "more sturdy", or to hold the two electrodes sets at a "fixed predetermined distance". This is facially implausible and counter to the teachings of the cited art which do not show insulation used for these purposes.

Alternatively, the Examiner suggests that the insulation would be used to prevent a shorting of two electrodes sets held in opposition and operated so that current flows between them. But the cited prior art Gough teaches that an un-insulated shaft can be used exactly in this context without shorting. See Gough, column 8, lines 9-12. It is not clear if there is any objective basis for the Examiner's position.

The Applicant has been subject to a prolonged set of murky rejections during which time later filed European and Japanese counterpart applications have been allowed. A goal of the Pre-Appeal Brief Conference Program is to spare the Applicant the added time and expense of an Appeal Brief and to conserve the resources of the Board of Appeals when essential elements of a *prima facie* rejection are clearly missing. In this case, the Examiner has failed to make a *prima facie* case of obviousness by ignoring the teachings of the prior art, applying improper legal standards to the claim limitations, and relying on unsupported and implausible assertions about motivations of those in this art.

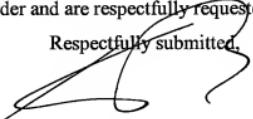
Remarks Accompany Pre-Appeal Brief Request for Review

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Reconsideration by the Panel, withdrawal of the rejections, and allowance of the application are therefore believed in order and are respectfully requested.

Respectfully submitted,


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